

Economic Impact Statement

LSA Document #06-426

IC 4-22-2.1-5 Statement Concerning Rules Affecting Small Businesses**Description of the Rule**

Amends [410 IAC 1-4-8](#) to update sterilization requirements. Currently the rule requires covered individuals to document that biological indicators for sterilization equipment were used within 30 days of the current sterilization procedure. The amendment will require documentation that biological indicators were used seven days prior to the current sterilization procedure. Effective 30 days after filing with the Publisher.

Economic Impact on Small Businesses**1. Estimate of the number of small businesses, classified by industry sector, that will be subject to the proposed rule.**

The Indiana State Department of Health (ISDH) is unable to provide a precise estimate of the number of individuals affected by this rule. The ISDH estimates the current number of individuals who have professional, employment, or volunteer duties that require the individual to have direct contact with blood or other body fluids as part of their medical, public health, or public safety duties exceeds 300,000. The ISDH estimates over 20,000 facilities may be affected due to the provision of services that may include exposure to blood or other body fluids.

2. Estimate of the average annual reporting, record keeping, and other administrative costs that small businesses will incur to comply with the proposed rule.

The proposed amendment to the Universal Precautions Rule does not add any annual reporting, record keeping, or other administrative costs for small businesses to comply with the rule.

3. Estimate of the total annual economic impact that compliance with the proposed rule will have on all small businesses subject to the rule.

The proposed amendment to the Universal Precautions Rule does not increase the economic impact on small business for complying with the rule.

4. Statement justifying any requirement or cost that is imposed on small businesses by the rule; and not expressly required by the statute authorizing the agency to adopt the rule; or any other state or federal law.

The proposed amendment to the Universal Precautions Rule conforms with accreditation requirements set by American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF), Occupational Safety and Health Administration (OSHA), Association for Advancement of Medical Instrumentation (AAMI), Centers for Disease Control (CDC), Joint Commission on Accreditation of Healthcare Organizations (JCAHO), Association of Perioperative Registered Nurses (AORN), American Dental Association (ADA), and American Hospital Association (AHA) and does not add any burden to facilities. Professionals should not compromise on patient safety or regulations that reduce the incidence of infections. Failure to comply with universal precautions will increase the likelihood that an individual who is exposed to blood or body fluid will acquire a dangerous communicable disease.

5. Regulatory Flexibility Analysis

Other factors considered:

A. Establishment of less stringent compliance or reporting requirements for small businesses.

The proposed amendment provides updated requirements based on best practices. Through the accreditation program, the highest quality of patient care that serves the medical community and the public interest is achieved. Less stringent requirements would increase the likelihood that an individual exposed to blood or body fluids would acquire a dangerous communicable disease such as HBV. The average annual cost of approved HBV therapy is \$24,000 for a single drug. Estimated charges for liver transplantation would be \$392,800, with annual follow-up charge of \$21,900.

B. Establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses.

The proposed amendment does not change schedules or deadlines for compliance or reporting requirements.

C. Consolidation or simplification of compliance or reporting requirements for small businesses.

There are no new reporting requirements imposed by the proposed amendment to the rule.

D. Establishment of performance standards for small businesses instead of design or operational standards imposed on other regulated entities by the rule.

Universal precautions are best practices for the prevention of the spread of dangerous communicable disease through contact with blood or body fluids.

E. Exemption of small businesses from part or all of the requirements or costs imposed by the rule.

Exposure to dangerous communicable disease through blood or body fluids is a risk for small and large businesses.

Conclusion

The proposed amendment provides updated requirements based on best practice. Less stringent requirements would increase the likelihood that an individual exposed to blood or body fluids would acquire a dangerous communicable disease. The amendment does not require additional costs for small businesses.

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